Claims 1-19 have been rejected under either 35 U.S.C. § 102(e) or 35 U.S.C. § 103(a) as being anticipated or obvious in view of Purchio et al (U.S. 5,599,788; hereinafter "Purchio").

Applicants have amended claim 1 to recite a dressing in which the biodegradable cell anchoring layer is a specific polyanionic or polycationic material, e.g., heparin or polylysine (e.g., claim 11). The cell anchoring layer provides good anchoring for cells while also providing readily controlled biodegradation.

Claims 2 as amended is now limited to a specific dressing in which a cell-adherent carrier for a cell tissue, that is to be incorporated into a body region after application of the dressing, is expressly made cell-abherent, thereby ensuring that cells are readily shed from the surface.

There are major differences in mode of use of the present cell tissue dressing and that of the H3 protein source of Purchio. These differences make the present invention novel and not obvious over Purchio for reasons as stated below.

The present invention effectively performs as a controlled release tissue graft dressing which is intended to optimize the transfer of a tissue culture anchored to a dressing from the dressing onto a body region, e.g., a wound, to be incorporated into the body region at a desired rate and to a desired degree.

In brief, the dressing uses a combination of:

i) a layer of cell tissue to be transferred onto a wound from the dressing;

ii) securely anchored to a cell-abherent anchoring layer;

iii) by a selected biodegradable cell-adherent anchoring layer.

In detail, key novel features of the present cell tissue dressing include that the present dressing has a carrier for a cell tissue that is to be incorporated into a body region after application of the dressing. Further, the present cell-bearing surface of the carrier for a cell tissue dressing which is conventionally strongly cell-adherent is expressly cell-abherent. The abherent nature of the present cell-bearing surface ensures that no cells can anchor to the surface and all cells are readily shed from it.

Preferably, a surface of a cell-adherent carrier is expressly made cell-abherent, which deliberately alters the surface properties to ensure that no cells can anchor to the surface and all cells are readily shed from it.

Again expressly, the abherent surface is then made cell-adherent by coating it with a biodegradable cell-anchoring layer of specific polyionic material, e.g., of heparin or polylysine. This is selected to provide a surface that is strongly cell-adherent, but at the same time can biodegrade after application at a desired rate and to a desired degree.

Before application of the dressing to a wound, cell tissue is grown on the cell-anchoring layer (see pages 10, 11, passim of the present application), and is securely anchored to the carrier by the selected cell-adherent anchoring layer.

The cell-anchoring layer with the surface that is cell-adherent biodegrades after application to expose the cell tissue to a dressing carrier surface that is non-cell-adherent. The biodegradable nature of the cell-anchoring layer ensures ready release of anchored cells as these are incorporated into the adjacent body region at a desired rate and to a desired degree.

The present invention also provides a parallel method of treating the mammalian body with a cell tissue dressing of the present invention, and a system and method for preparing a cell tissue dressing of the present invention.

The differences between the features of the present cell tissue dressing and those of the H3 protein source of Purchio arise from the differences between their intended uses. Purchio's H3 protein source is agreed to have a layer of biodegradable material, but it is specifically and uniquely H3 protein. Thus (by the same token), Purchio fails to disclose the present cell-adherent materials on the carrier surface. (See, e.g., cols. 4 and 5, passim, and all the Examples, which disclose none of the present cell-adherent materials, and only H3).

Accordingly, the cell tissue dressing of the present invention is clearly novel over the H3 protein source of Purchio.

For the same reason, the present claims 17 and 19 to a system for a cell tissue dressing and a method for preparing a cell tissue dressing of the present invention are clearly novel over Purchio, as is the present claim 18 to a method of treating the mammalian body with such a tissue dressing.

Furthermore, the dependent claims recite further novel elements not disclosed nor made obvious by Purchio. For example, in claim 2, the biodegradable layer is expressly disposed on a carrier surface that is inherently cell-adherent, but has been made into a cell-abherent carrier surface, which deliberately alters the surface properties to ensure that no cells can anchor to the surface and all cells are readily shed from it.

No reference can be found in Purchio to teach a skilled person anything about an inherently cell-adherent carrier that has a surface that is an abherent surface. Although inherently cell-adherent materials, e.g., gelatin and catgut, are disclosed in Purchio, at col. 2, lines 33-37, and 41-46, Purchio fails to say that the cell-adherent materials should be selected to be provided with a wound-facing surface that is a cell-abherent carrier surface.

Accordingly, the cell tissue dressing of claim 2 is also clearly novel over the H3 protein source of Purchio.

With respect to the 35 U.S.C. § 103(a) obviousness rejection, when Purchio is read as a whole, it is clear that the disclosure in Purchio is limited to the H3 protein source, and thus the main thrust of Purchio is just to providing:

a) H3 protein to promote the mutual adhesion of cell tissue (such as keratinocytes and/or fibroblasts in a wound) to promote wound healing (see col. 2, lines 16-20, and col. 4, passim, and all the Examples);

b) H3 protein sources (col. 2, lines 52-57); and

c) a method of treatment with such sources (col. 2, lines 52-57).

The secondary thrust of Purchio is directed to the use of H3 protein to ensure that cells are securely anchored to a carrier by H3 (col. 2, lines 21-26).

Nowhere does Purchio even contemplate or suggest the nub of the present invention, i.e., a controlled release tissue graft dressing intended to optimize the transfer of a tissue culture anchored to a dressing from the dressing onto a body region, e.g., a wound, to be incorporated into the body region at a desired rate and to a desired degree.

Further, Purchio does not contemplate or suggest a combination of:

a) a layer of cell tissue to be transferred onto a wound from the dressing;

b) securely anchored to a cell-abherent carrier;

c) by a selected biodegradable cell-adherent material

to achieve this.

Thus, Purchio fails to even contemplate or suggest any need for a tissue of cells of any sort to be transferred from a dressing to a wound, as in the present invention, to be incorporated into the adjacent body region.

Consequently, there is no teaching or suggestion in Purchio about providing a carrier surface that is cell-abherent to facilitate the release of cells as these are incorporated into the adjacent body region.

A skilled person seeking to achieve the desired present outcome is not even taught or motivated for any need to turn to cell-adherent materials that is strongly cell-adherent, but at the same time can biodegrade after application at a desired rate and to a desired degree.

Further, there fails to be any teaching or suggestion in Purchio that H3 has any useful biodegradable properties, let alone to select a cell-adherent material such as H3 because of H3's useful biodegradable properties.

More specifically, Purchio is completely silent and teaches or suggests absolutely nothing about the concept of selecting a cell-adherent material such as the present specific polyionic material, e.g., heparin or polylysine:

a) to provide a surface that is strongly cell-adherent, but

b) which at the same time can biodegrade after application at a desired rate and to a desired degree.

There is no teaching or suggestion whatsoever in Purchio of the combination of:

i) a dressing with a biodegradable cell-anchoring layer, and

ii) a cell-abherent carrier surface that releases adherent cells as the cell-anchoring layer biodegrades after application

to achieve a desired rate and degree of release of a layer of cell tissue to be transferred onto a wound from the dressing.

Moreover, Purchio clearly teaches away from providing H3 protein as a cell-adherent material on a carrier surface that usefully biodegrades after application to cause cell transfer.

Thus, from the penultimate paragraph in col. 4 to the second paragraph of col. 5, Purchio teaches that preferably promotion of healing is carried out using a method of treatment with H3 protein sources that are free of (redundant) cells.

Where Purchio is directed to the use of H3 protein to adhere cells to an anchoring surface, the emphasis is that the attachment of the cells to the carrier is enhanced by H3 (col. 2, lines 21-26); there is no teaching of any release to optimize the transfer of a tissue culture anchored to it.

The cell tissue dressing and method of treating the mammalian body with a cell tissue dressing of the present invention are accordingly clearly novel over Purchio, as are the system and method for preparing the dressing.

Accordingly, it is clear that the Examiner's rejection of claims on the basis of the Purchio reference is improper and should be withdrawn.

In view of the foregoing, it is respectfully submitted that the present application is in condition for immediate allowance, and such action is earnestly solicited.

Respectfully submitted,

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ATTACHMENT B

Marked Up Replacement Claims

Following herewith is a marked up copy of each rewritten claim.

1. (Twice Amended) A wound dressing comprising a carrier layer having a wound-facing surface, said surface being non-adherent to anchorage-dependent cells and having disposed thereon a biodegradable cell anchoring layer~~, said anchoring layer having anchored thereto mammalian cells which form a cell layer~~ comprising one of

(i) a polyanion selected from the group consisting of a heparin, an inositol phosphate, fucoidin, syndecan, betaglycan, perlecan, dextran sulphate, pentosan, mesoglycan and polyvinyl sulphate; and

(ii) a polycation comprising a polypeptide; and

said anchoring layer having anchored thereto mammalian cells which form a cell layer comprising one of keratinocytes and fibroblasts.

2. (Amended) The wound dressing of claim 1 wherein the carrier layer comprises a polymeric material adherent to anchorage dependent cells and treated on the wound facing surface thereof to be non-adherent to cells, said polymeric material comprising a polymer selected from a group consisting of polyhydroxyethylmethacrylic acids, cross-lined polyvinylalcohols, polyacrylic acids cross-linked with trialkylsucrose, polyvinylpyrrolidones, polyetherpolyesters, polyetherpolyamides, polycrylamides, polyethylene oxide, polyurethanes and ethylenevinyl acetate copolymers.

6. (Twice Amended) The wound dressing of claim ~~4~~ 2 wherein the wound facing surface is treated with a phosphocholine, a silicone, a polyethylene glycol or a polytetrafluroethylene.

8. (Amended) The wound dressing of claim ~~7~~ 1 wherein the polyanion moiety has anchored thereto a cell adhesion protein.

11. (Amended) The wound dressing of claim ~~10~~ 1 wherein the polypeptide is polylysine.

14. (Amended) The wound dressing of claim ~~12~~ 1 wherein the cell layer comprises both keratinocytes and fibroblasts.

17. (Amended) A cell culture system comprising:

(a) a wound dressing comprising a carrier layer having a wound-facing surface, said surface being non-adherent to anchorage dependent cells and having disposed thereon a biodegradable cell anchoring layer comprising one of

(i) a polyanion selected from the group consisting of a heparin, an inositol phosphate, fucoidin, syndecan, betaglycan, perlecan, dextran sulphate, pentosan, mesoglycan and polyvinyl sulphate; and

(ii) a polycation comprising a polypeptide; and

(b) a vessel having interior and exterior surfaces for containing a liquid culture medium for culturing cells and the dressing.

18. (Amended) A method of treating a skin trauma site on a mammalian patient comprising the step of applying to a patient a wound dressing ~~which~~, said dressing comprises~~;~~:

(a) a carrier layer comprising a wound surface which is non-adherent to anchorage dependent cells and having disposed thereon a biodegradable cell anchoring layer comprising one of

(i) a polyanion selected from the group consisting of a heparin, an inositol phosphate, fucoidin, syndecan, betaglycan, perlecan, dextran sulphate, pentosan, mesoglycan and polyvinyl sulphate; and

(ii) a polycation comprising a polypeptide; and

(b) a layer of mammalian cells comprising one of keratinocytes and fibroblasts anchored to the anchoring layer.

19. A method of preparing a wound dressing comprising the steps of~~;~~:

(a) obtaining a surface which is non-adherent to the anchorage dependent cells on a wound facing surface of a carrier layer;

(b) forming a biodegradable cell anchoring layer on a non-adherent to anchorage dependent cells surface of a carrier layer, said anchoring layer comprising one of

(i) a polyanion selected from the group consisting of a heparin, an inositol phosphate, fucoidin, syndecan, betaglycan, perlecan, dextran sulphate, pentosan, mesoglycan and polyvinyl sulphate; and

(ii) a polycation comprising a polypeptide;

(c) culturing a carrier layer which comprises a non-adherent to anchorage dependent cell surface and biodegradable cell anchoring layer in the presence of mammalian cells comprising one of keratinocytes and fibroblasts.